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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,337	12/19/2001	Stefan L. J. Masure	JAB-1512	1691

7590 10/07/2004

EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	

Philip S Johnson
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,337	MASURE ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-19,21-23 and 29-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-6,8-19,21-23 and 29-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Sequence Compliance

1. The reply filed on 6/27/03 is not fully responsive to the previous requirement for compliance with the Sequence Rules, nor was the amendment to the claims on 12/19/01 in compliance with the new AIPA rules under 37 CFR 1.121(a) and (b) on the proper procedure for submitting amendments to the specification or the claims after March 1, 2001. For example, replacement paragraphs/claims are now required under 37 CFR 1.121(a) or (b). In other words, a complete copy of all claims (i.e., including what claims are cancelled), which also indicates where the submitted changes to the amended claims exists, is required.

In summary, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately in the* "Sequence listing" ***and in the text of the description*** and *claims whenever described.* For example, the appropriate SEQ ID NOs must be recited in the figure legends for Figures 2 & 3 on pages 21-22 of the specification. Pages 24, 27 & 35 also need to be amended to indicate the appropriate SEQ ID NOs; especially since it is unclear if any SEQ ID NOs exist for these nucleotide sequences, as required. Lastly, any GenBank/EMBL Accession NOs that possess a SEQ ID NO within the instant specification must be indicated within the specification when described. See MPEP 2422 & 2431. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Note that failure to respond to both the requirements for sequence compliance and the restriction requirement below will be held as *nonresponsive*, and may result in *abandonment* of this application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group Ia-g, claim(s) 1-6, 9-12, 17 & 47, drawn to nucleic acids encoding a GDNF family receptor member (GFRα-4), vectors, host cells, and methods of producing these growth factors, as it relates to either SEQ ID NO: 1, 2, 3, 4, 5, 6 or 7. Note that fragments of a larger SEQ ID NO may be rejoined with that elected, but a specific SEQ ID NO must still be elected.

Group IIa-b, claim(s) 8, 16 & 21, drawn to a GDNF family receptor member (GFRα-4) polypeptide, as it relates to either SEQ ID NO: 8 or 9. Note a specific SEQ ID NO must be elected.

Group III, claim(s) 13-15, drawn to transgenic animals/tissue.

Group IV, claim(s) 18-19, 22-23 & 45, drawn to antisense polynucleotides/probes and pharmaceutical compositions thereof.

Group V, claim(s) 29, 38-40, 43-44 & 46, drawn to methods of identifying agonists, ligands or antagonists to GFRα-4, and kits thereof.

Group VI, claim(s) 30, drawn to methods of producing an agonist or antagonist to GFRα-4.

Group VII, claim(s) 31 & 41-42, drawn to pharmaceutical compositions of agonists to GFRα-4.

Group VIII, claim(s) 32 & 48, drawn to methods of promoting GFRα-4 activation in a mammal comprising administering agonists of GFRα-4.

Group IX, claim(s) 33, drawn to pharmaceutical compositions of antagonists to GFRα-4.

Group X, claim(s) 34 & 49, drawn to methods of limiting activation of GFRα-4 in mammal comprising administering antagonists of GFRα-4.

Group XI, claim(s) 36-37, drawn to antibodies to GFRα-4.

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is directed to to nucleic acids encoding a GDNF family receptor member (GFRα-4), vectors, host cells, and methods of producing these growth factors, as it relates to either SEQ ID NO: 1, 2, 3, 4, 5, 6 or 7; which is the first product and the first method of using this product. However, because Thompson et al (1988) teach nucleic acids encoding a GDNF family receptor member (GFRα-4), which meets the recited claim limitations of claim 1, no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Groups Ia-g, IIa-b, III, IV, VII, IX & XI are also drawn to a structurally different products, which do not require each other for their practice and do not share the same or a corresponding technical feature. The technical features of Groups V-VI, VIII & X are drawn to methods having different goals, method steps and starting materials, which do not require each other for their practice and do not share the same or a corresponding technical feature. Note that PCT Rule 13 does not provide for multiple products or methods within a single application. Because the technical feature of Group Ia-g is not a special technical feature, and because the technical features of the Groups II-XI inventions are not present in the Group I claims, unity of invention is lacking.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
October 1, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER